EXHIBIT E

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming Products Liability Litigation	MDL No. 15-2666 (JNE/FLN)
This Document Relates to All Actions	**EXPERT REPORT OF DAN KOENIGSHOFER, MSPH, PE**

I. Educational Background, Training & Experience

I was raised in Los Angeles, where as a child, I suffered from asthma, allergies, and loss of outdoor play time exacerbated by smog. I received a Bachelor of Science in Physics with a minor in Meteorology from University of California, Davis and a Master's of Science in Public Health, Air and Industrial Hygiene, from University of North Carolina - Chapel Hill. My thesis involved modeling of macro air movement and sampling of rainwater. This resulted in my first publication, *Long Range Transport of Trace Metals in Rainwater*, APCA 1975. Classes included: particle physics, air chemistry, water chemistry, industrial ventilation, optics, epidemiology, atmospheric modeling, air pollution control, and biostatistics. My first jobs were at an air pollution testing and engineering firm and the U.S. Environmental Protection Agency ("EPA"). I started my consulting firm in May, 1976 working on a variety of projects: solar homes,

schools, churches, laboratories, pharmaceutical, and hospitals. Around 1990 I decided to specialize in hospital engineering and have continued that to this day. I currently work half time for an engineering firm and part time for a contractor – all healthcare projects. I have written numerous articles and a book on Hospital HVAC Design.

I have been active in the American Society of Heating, Ventilating, and Refrigeration Engineers (ASHRAE) since 2003. I was motivated by their intention to produce a guide book for ventilation in hospitals. Since then I have attended all but one of their twice-annual meetings, as an active participant and more recently as a member of the committee. This is the committee that produced Standard 170-2008 & 2013. Ventilation of Health Care Facilities. In 2006, ASHRAE asked me to produce materials for and teach a class on designing hospital HVAC systems. Subsequently, I've taught 3, 6, & 12 hour classes at meetings in approximately 30 major U.S. cities and Istanbul, Mexico City, and Mumbai. In 2010 ASHRAE asked me to lead a group to rewrite the book, HVAC Design Guide for Hospitals and Clinics (2003). Early on, our committee determined significant revisions were appropriate. Our committee dedicated over three years draft and finalize the new edition. I am the primary author of Chapter 2: Infection Control and Chapter 8. Room Design (including section on Operating Rooms). As the editor-in-chief I was also the final arbitrator of discussions and responsible for editing the entire book.

In 2012, I was designated a "Senior" in the American Society of Hospital Engineers (SASHE). This award is based on publications and active participation.

I have attached a copy of my CV as Exhibit A to this report.

II. THE QUESTION PRESENTED

I was asked to explain the environment of use for the Bair Hugger device - hospital operating room – including how an operating room ventilation system is designed to minimize the risk of particles and infection. Additionally I have been asked to offer my opinion on the impact, if any, of the Bair Hugger device on the protective effect of the hospital HVAC system.

III. THE ENVIRONMENT OF USE: HVAC SYSTEM DESIGN AND FUNCTION IN OPERATING ROOMS

1. Abstract

HVAC systems provide comfort and quality air for patients, staff, and visitors in hospitals. Comfort is generally determined by temperature, humidity, and air speed. Air quality is generally defined by particle count (both organic and inorganic). ASHRAE Standard 170 ("Standard 170") specifies *minimum* levels of filtration, pressurization, air change rates, and outside air for dilution. Specific criteria are provided for operating rooms and most spaces in a hospital. Standard 170 also provides additional guidance for the design of OR's and other critical areas. As with all codes, ASHRAE Standard 170 provides only the *minimum* standards to design hospitals. This report discusses some of the purposes and the challenges of meeting the standard. Standard 170 is a design guide, it does little to address day to day operations, maintenance, and activities of medical staff within the rooms. Medical care professionals and anyone designing machines for

use in an operating room should be aware of the environment of use, and consider the potential for compromising the function of the HVAC system to provide high quality air to the patient and surgical site.

2. **Hospital HVAC Design Standards**

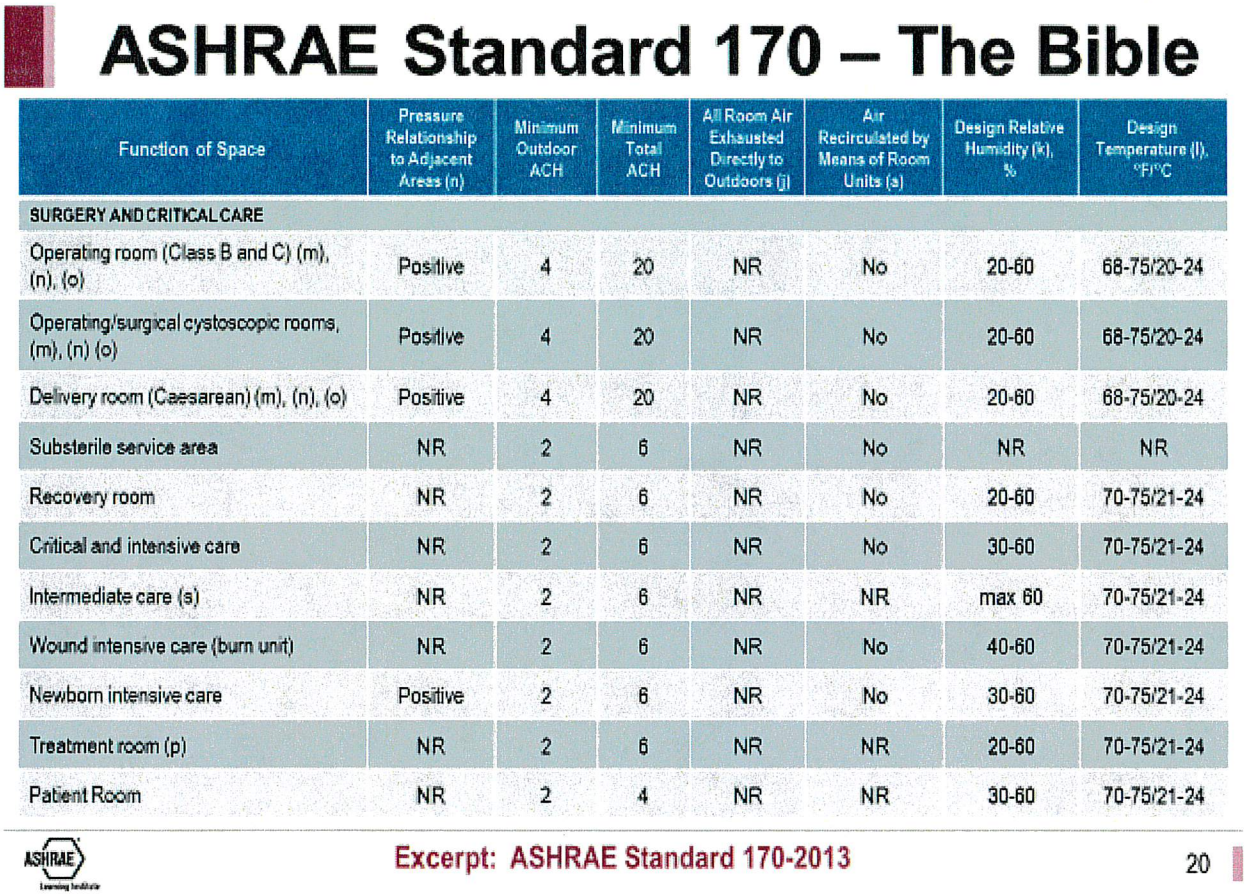
The American Society of Heating, Refrigeration, and Air Conditioning Engineers (ASHRAE) is generally recognized as the world leader in establishing standards and training for the design of Heating Ventilating and Air Conditioning (HVAC) systems. The standards most frequently used in health care engineering are:

- ASHRAE Standard 170 Ventilation of Health Care Facilities (building code in ~40 states)
- ASHRAE Standard 55 Human Comfort
- ASHRAE Standard 52 Air Filtration
- ASHRAE book: HVAC Design Manual for Hospitals and Clinics

The American Society of Hospital Engineers (ASHE) is part of the American Hospital Association. ASHE publishes guidelines for the construction, operation, and maintenance of health care facilities. Various clinical associations publish guidelines which occasionally affect hospital HVAC design. ASHRAE is working to coordinate and incorporate some of the HVAC portions of these guidelines into Standard 170.

The following is an excerpt from Standard 170. As shown, it calls out the pressurization, rate of dilution with outside air (OA), supply air (SA) rate, whether or not the air may be recirculated, humidity range, and temperature range for different spaces. The full table includes ~125 space types. Of course, Operating Rooms (OR's) are

generally considered the most critical spaces and receive the most attention. The typical OR will cost $1-2 million to build. The HVAC system alone is generally 40-50% of the cost.



Function of Space	Pressure Relationship to Adjacent Areas (n)	Minimum Outdoor ACH	Minimum Total ACH	All Room Air Exhausted Directly to Outdoors (j)	Air Recirculated by Means of Room Units (a)	Design Relative Humidity (k), %	Design Temperature (l), °F/°C
SURGERY AND CRITICAL CARE							
Operating room (Class B and C) (m), (n), (o)	Positive	4	20	NR	No	20-60	68-75/20-24
Operating/surgical cystoscopic rooms, (m), (n) (o)	Positive	4	20	NR	No	20-60	68-75/20-24
Delivery room (Caesarean) (m), (n), (o)	Positive	4	20	NR	No	20-60	68-75/20-24
Substerile service area	NR	2	6	NR	No	NR	NR
Recovery room	NR	2	6	NR	No	20-60	70-75/21-24
Critical and intensive care	NR	2	6	NR	No	30-60	70-75/21-24
Intermediate care (s)	NR	2	6	NR	NR	max 60	70-75/21-24
Wound intensive care (burn unit)	NR	2	6	NR	No	40-60	70-75/21-24
Newborn intensive care	Positive	2	6	NR	No	30-60	70-75/21-24
Treatment room (p)	NR	2	6	NR	NR	20-60	70-75/21-24
Patient Room	NR	2	4	NR	NR	30-60	70-75/21-24

Figure 1. Standard 170 Room Requirements

Standard 170 is a minimum HVAC design guide whose objective is to "provide environmental control for comfort, asepsis, and odor in health care facilities". Asepsis is "the state of being free of pathogenic microorganisms or the processes for removing pathogenic organisms". While most engineers agree on these objectives, there is some debate about the specific values and techniques prescribed in Standard 170. As with all

discussions at ASHRAE, engineers are balancing known potential risks to patients alongside financial considerations raised by hospitals. The following figure lists some of the elements of Standard 170 that are the subject of ongoing research and debate in the HVAC engineering community.

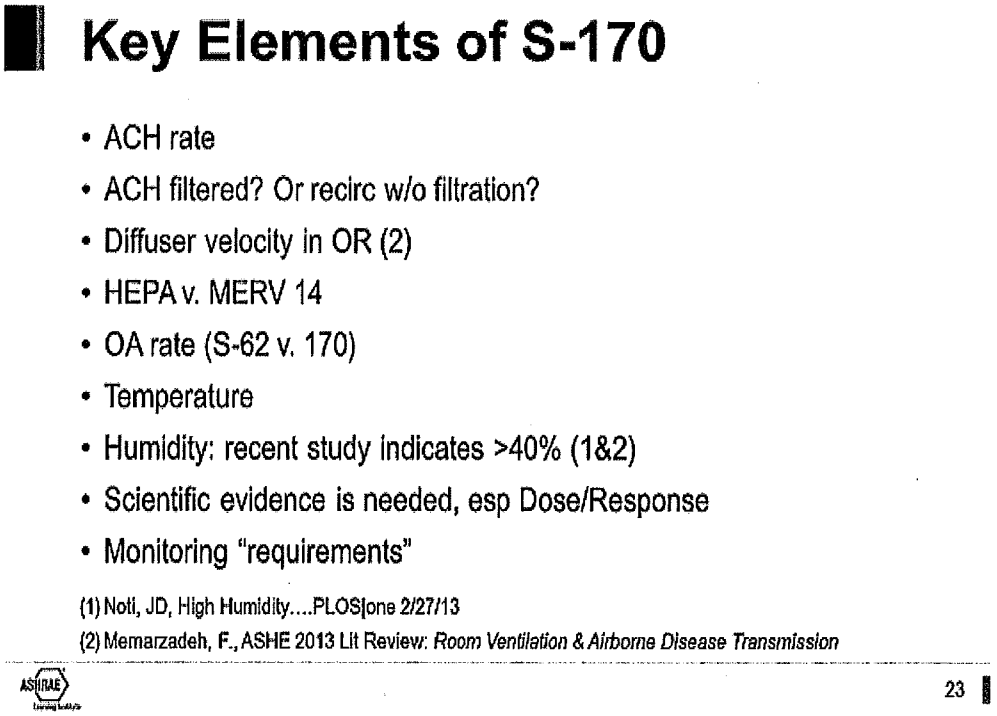


Figure 2

3. **Infection Control**

The primary purpose of the hospital HVAC system is to provide and maintain air quality. Hospital associated infections (HAI) cost billions of dollars each year. While there are many sources of microorganisms, most experts agree that airborne sources of infection are responsible for 5-15% of HAI. These airborne infections are estimated to cost in excess of $500 million each year. It is the task of hospital HVAC engineers to

mitigate the incidence of airborne HAI. Figure 3 lists some of the generally recognized modes of transmission by which and HAI can infect patients and/or hospital staff.

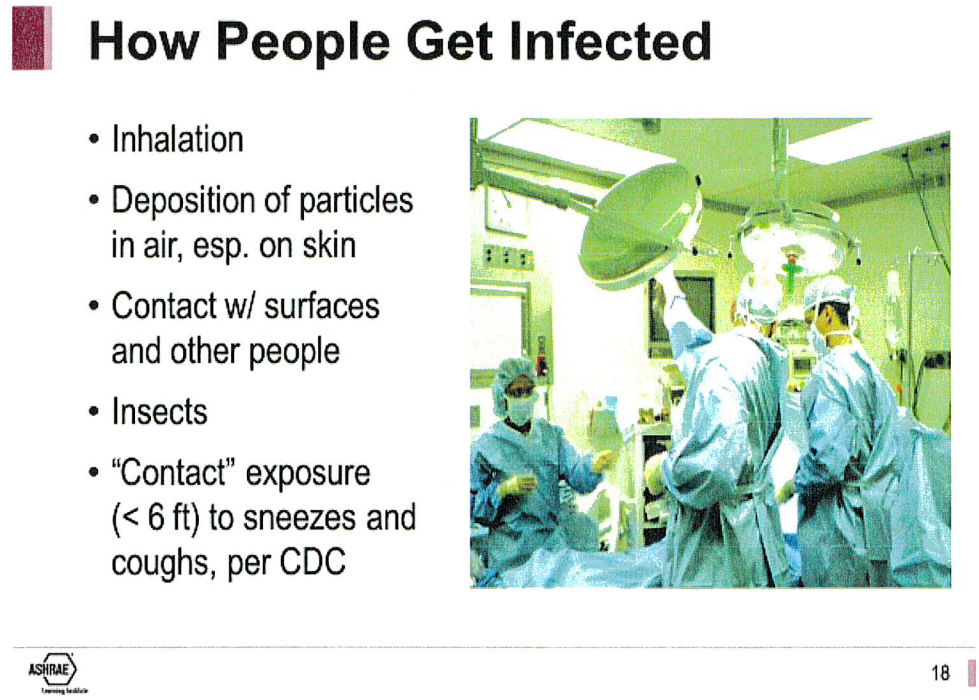


Figure 3. Methods of Infection

The most serious type of HAI is Surgical Site Infection (SSI). These are generally understood to be most often caused by deposition of particles directly into the wound or insertion of instruments or hands which are contaminated. A simple, conceptual equation for the probability of infection follows:

Figure 3. Infection Equation:

$$\text{Infection} = \frac{\text{Dose x Site x Virulence x Time}}{\text{Level of Host Defense}}$$

4. **Dose**

Generally, bacteria and viruses ride on larger particles and aerosols. These might be skin particles, dust, sneeze/cough aerosols, spores, and even insects (mites). At this

time, there is no single accepted method to measure pathogenic microorganisms in the air in real time. Rather, it is generally understood and accepted that the best surrogate for air quality is to measure particles. The HVAC system can reduce the density of particles in the room by introducing clean air. As shown in the following table, the rate of air changes of clean air is directly related to the residence time of the particles (the "fly") in the room. The goal of an HVAC engineer is to quickly clear the "fly" from the room. This is accomplished by changing the air in the room. Thus, the higher the supply air flow, the greater the air change per hour (ACH) and the faster the removal of airborne particles (flies).

Dilution (Fly in Room)

ACH	Minutes required for removal of 90%	Minutes required for removal of 99%	Minutes required for removal of 99.9%
2	69	138	207
4	35	69	104
6	23	46	69
8	17	35	52
10	14	28	41
12	12	23	35
15	9	18	28
20	7	14	21
50	3	6	8

CDC MMWR 2005, *Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Settings*, 2005 Table 1

ASHRAE 2323

Figure 4. Theoretical Effect of Air Changes on Particle Count

*assuming perfect mixing, perfectly clean SA, and no particle generation in the room

Figure 5 shows the settling rate of different size particles. As indicated, small particles stay in suspension for hours while particles the size of skin squames (10 micron) will settle in minutes. Thus, it is reasonable to conclude that squames shed during surgery would drop to, and stay, on the floor absent other mechanisms and turbulence.

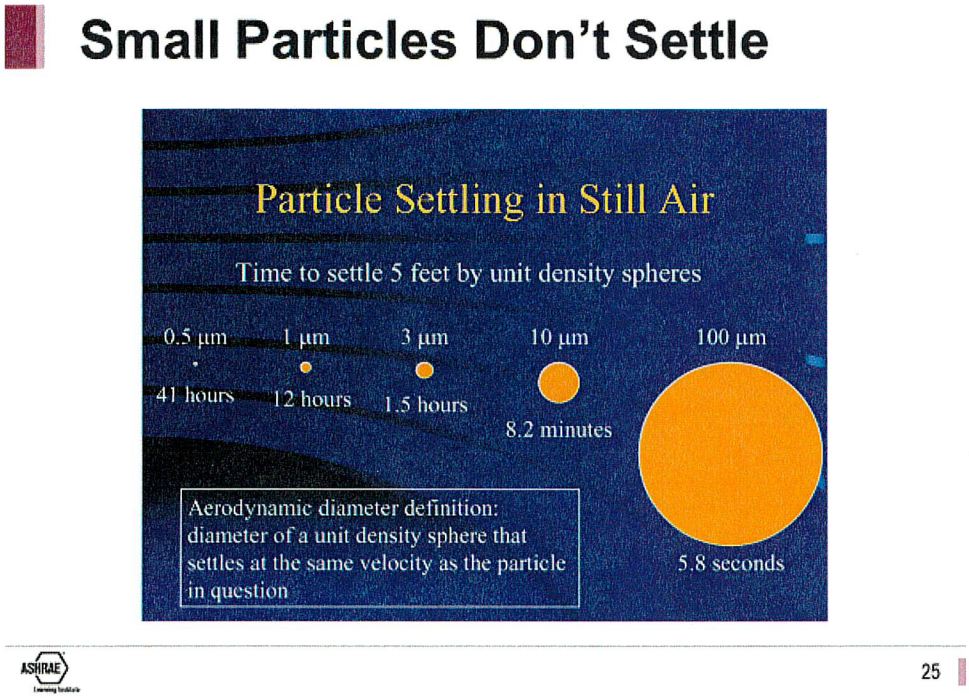


Figure 5. Particle Settling Rate v. Size

The HVAC system is also designed to move particles and odors out of the hospital in a logical path, as shown in Figure 6. The idea is to design the HVAC system so the cleanest air is introduced to the operating rooms and other sensitive areas, then moved via pressure difference to less clean areas and eventually out of the hospital.

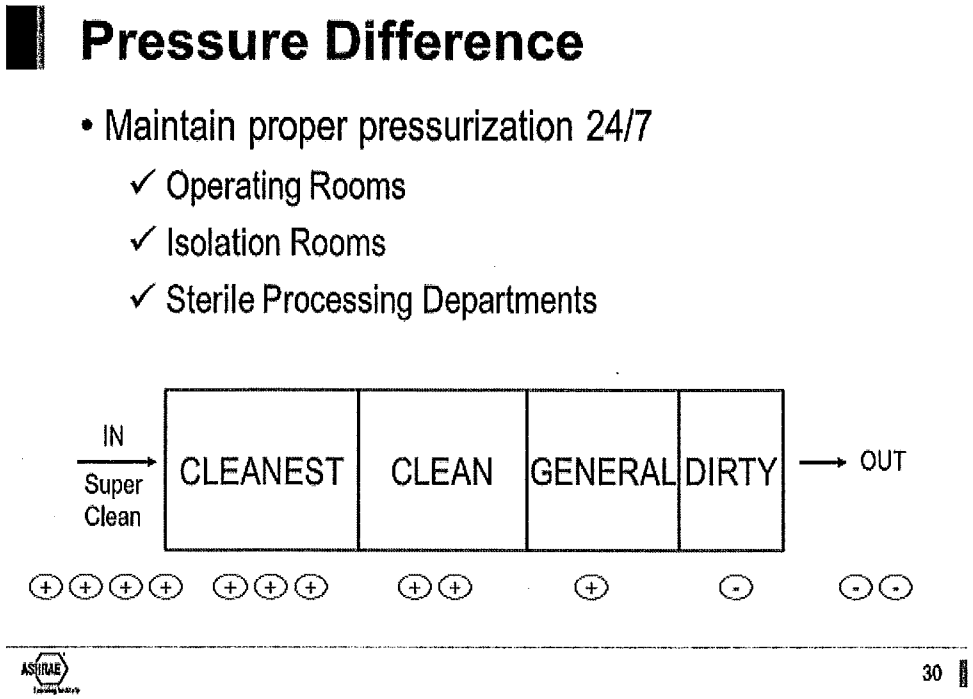


Figure 6. Moving Air via Pressure Differentials

Another way to reduce "dose" is by recirculating air through high quality filters. As shown in Figure 1, 20% (4 of 20 ACH[1]) of the supply air must be outside air (OA). Thus, in theory every "puff" of air is filtered 5 times before it is removed from the OR. HVAC engineers presume filtered air is cleaner than outside air. The following ASHRAE tables show the required *minimum* filter efficiencies for different parts of health facilities and the capture efficiency of various MERV filters. MERV is a measure of filter efficiency with a scale of 1-20. MERV 17 is commonly used in hospitals and often referred to as High Efficiency Particle Arrestance (HEPA). As shown in Figure 8, MERV 17 (HEPA filter) is 99.97% efficient for all particles down to 0.3 micron. MERV

[1] ACH or "Air Changes per Hour"

14 is the minimum recommended final filter serving operating rooms. Many hospitals, however, specify HEPA as the best practice.

While the factory MERV rating is required, it is essential that the final filter be installed correctly. For any filter to work effectively, it must have a tight gasket and be seated flat. The rack must not be bent or out of square. Even the smallest breach of the filter assembly will allow unfiltered air to bypass a filter. The Standard 170 committee is presently considering adding a requirement for efficiency testing after every filter change.

ASHRAE Filtration Standard 170-2013

Space Designation (According to Function)	Filter Bank #1 (MERV)[a]	Filter Bank #2 (MERV)[a]
Operating rooms (Class B and C surgery); inpatient and ambulatory diagnostic and therapeutic radiology; inpatient delivery and recovery spaces	7	14
Inpatient care, treatment, and diagnosis, and those spaces providing direct service or clean supplies and clean processing (except as noted below); All (rooms)	7	14
Protective Environment (PE) rooms	7	HEPA[c,d]
Laboratories; Procedure rooms (Class A surgery), and associated semirestricted spaces	13[b]	NR
Administrative; bulk storage, soiled holding spaces; food preparation spaces, and laundries	7	NR
All other outpatient spaces	7	NR
Nursing facilities	13	NR
Psychiatric hospitals	7	NR
Resident care, treatment, and support areas in inpatient hospice facilities	13	NR
Resident care, treatment, and support areas in assisted living facilities	7	NR

*N/R = not required

a. The minimum efficiency reporting (MERV) is based on the method of testing described in *ANSI/ASHRAE Standard 52.2-2012, Methods of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size* (in Informative Appendix B).

b. Additional prefilters may be used to reduce maintenance for filters with efficiencies higher than MERV 7.

c. As an alternative, MERV-14 rated filters may be used in Filter Bank No. 2 if a tertiary terminal HEPA filter is provided for these spaces.

d. High-Efficiency Particulate Air (HEPA) filters are those filters that remove at least 99.97% of 0.3 micron-sized particles at the rated flow in accordance with the testing methods of IEST RP-CC001.3 (IEST[2005] in Informative Appendix B).

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Figure 7. Filtration Standard

TABLE 2: MINIMUM EFFICIENCY REPORTING VALUE (MERV) PARAMETERS

ASHRAE Standard 52.2				ASHRAE Standard 52.1	Application Guidelines		
MERV	Particle Size Removal Efficiency, Percent in Particle Size Range, µm			Dust-Spot Efficiency Percent	Particle Size and Typical Controlled Contaminant	Typical Applications	Typical Air Filter/Cleaner Type
	0.3 to 1	1 to 3	3 to 10				
20	≥ 99.999	in 0.1 – 0.2 µm particle size		—	**< 0.3 µm** Virus (unattached) Carbon dust Sea salt All combustion smoke	Electronics manufacturing Pharmaceutical manufacturing Carcinogenic materials	HEPA/ULPA Filters*
19	≥ 99.999	in 0.3 µm particle size		—			
18	≥ 99.99			—			
17	≥ 99.97			—			
16	> 95	> 95	> 95	—	**0.3-1 µm** All bacteria Droplet nuclei (sneeze) Cooking oil Most smoke Insecticide dust Most face powder Most paint pigments	Superior commercial buildings Hospital inpatient care General surgery	**Bag Filters** – Nonsupported (flexible) microfine fiberglass or synthetic media, 12 to 36 inches deep. **Box Filters** – Rigid style cartridge, 6 to 12 inches deep.
15	85-95	> 90	> 90	> 95			
14	75-85	> 90	> 90	90-95			
13	< 75	> 90	> 90	80-90			
12	—	> 80	> 90	70-75	**1-3 µm** Legionella Humidifier dust Lead dust Milled flour Auto emission particles Nebulizer drops	Superior residential Better commercial buildings Hospital laboratories	**Pleated filters** –Extended surface with cotton or polyester media or both, 1 to 6 inches thick. **Box Filters** – Rigid style cartridge, 6 to 12 inches deep.
11	—	65-80	> 85	60-65			
10	—	50-65	> 85	50-55			
9	—	< 50	> 85	40-45			
8	—	—	> 70	30-35	**3-10 µm** Mold Spores Dust mite body parts and droppings Cat and dog dander Hair spray Fabric protector Dusting aids Pudding mix Powdered milk	Better residential Commercial buildings Industrial workplaces	**Pleated filters** –Extended surface with cotton or polyester media or both, 1 to 6 inches thick. **Cartridge filters** –Viscous cube or pocket filters **Throwaway** –Synthetic media panel filters
7	—	—	50-70	25-30			
6**	—	—	35-50	< 20			
5	—	—	20-35	< 20			
4	—	—	< 20	< 20	**> 10 µm** Pollen Dust mites Cockroach body parts and droppings Spanish moss Sanding dust Spray paint dust Textile fibers Carpet fibers	Minimum filtration Residential window air conditioners	**Throwaway** – Fiberglass or synthetic media panel, 1 inch thick. **Washable** – Aluminum mesh, foam rubber panel **Electrostatic** – Self-charging (passive) woven polycarbonate panel
3	—	—	< 20	< 20			
2	—	—	< 20	< 20			
1	—	—	< 20	< 20			

This table is adapted from ANSI/ASHRAE Standard 52.2-2007. [3]

Table 8. MERV Efficiency Parameters

5. **Site**

The likelihood a patient may contract an HAI is also affected by the site impacted by the particles. Particles landing on the skin are much less likely to cause infection than ones deposited in open wounds. Deep wounds are generally understood to be more susceptible than shallow wounds. Thus, the means of delivering the clean, filtered air may affect infections. As shown in the following figure, clean air is directed into the room through so called "laminar diffusers".[2] These are large metal arrays perforated with small holes. The intent is to deliver a gentle "waterfall" of clean air over the table. The area directly below this diffuser is referred to as the "sterile field."

Anything that disrupts this waterfall of sterile air reduces its effectiveness. Disruptions (turbulence) are caused by the surgeons and staff, objects (light booms, tables), thermal plumes (markedly hot or cold air), and air currents caused by devices, personnel, and doors.

6. **Virulence**

The HVAC system may have some limited effect on the virulence of microorganisms. Inside the air handling unit, sometimes UV lights are used to kill bacteria and algae growing on the wet surfaces. Some hospitals have taken on the additional effort of installing UV lights in ductwork, but the high speed of the air makes this ineffective. Some hospitals are now experimenting with portable UV lights which

[2] This intentional airflow is frequently called "laminar", though the airflow is not truly "laminar" from a physics perspective. .

are brought into unoccupied OR's to bathe the room in UV and kill microorganisms. Others have experimented with ozone.

There is much debate about the role of humidity in infections. There is good evidence that low humidity has adverse effects on humans over long terms. Unfortunately, there is no agreement on the exact length of time. Some point out that flu season coincides with low, winter humidity; but it is unclear if low humidity over hours or even days is harmful.

7. **Time**

As noted in Figure 4, the time that microorganisms spend in the OR is directly related to the supply air flow rate. Thus, the ACH required for OR's is a minimum of 20 air changes per hour. In most OR's this is a flow rate of 2,000 – 3,000 cfm (cubic feet/minute). Theoretically, 20 ACH will result in 99% flushing of the room within 14 minutes. Some hospitals require more ACH, and some hospitals are arguing for fewer ACH.

The early DHEW and DHHS publications required 100% outside air (OA). For the most part this requirement fell to political pressure after the oil embargo in the late '70's. Energy can be saved by reducing OA. The VA Hospitals retained the 100% OA requirement until the early 2000's. The current Standard 170 requirement is 4 ACH of outside air in OR's. Some hospitals and scientists are arguing to reduce this; again, motivated by the desire to reduce energy use, thereby reducing financial cost to run the HVAC system.

8. **Comfort**

Clearly, another purpose of the HVAC is to provide comfort for patients, staff, and visitors. Comfort is different for each person and highly dependent on clothing, age, health, activity, temperature, humidity, and air flow rate. Standard 55 bases comfort on surveys of occupants in a variety of conditions and defines "comfortable" as when 80% of the occupants are satisfied.

Surgeons often request temperatures below the Standard 170 (68F). This can create problems when the HVAC system is designed to the minimum. Thus, prudent design will allow temperatures as low as 63F in OR's. Unfortunately, in order to achieve lower temperatures, the HVAC system must provide more air and/or colder air. Cold air can create problems as it accelerates after leaving the diffuser. Again, this can disrupt the wound plume and increase turbulence.

The demand for low temperature is particularly common in orthopedic and cardiac OR's. These surgeries are can be lengthy and involve strenuous efforts by the surgeons. The gowns, caps, gloves, masks, etc. result in overheating the surgeons. Unfortunately, some of the other OR staff is often uncomfortably cold when the temperature is lowered.

These conflicting desires often cause difficulties for the HVAC design engineer and the operations personnel. It is the job of the designer to provide a system that can meet virtually all of the disparate temperature and humidity requests. It is the responsibility of the hospital engineer to operate the system as efficiently as possible while meeting the various user demands and code requirements.

Another implication of the surgeons demanding low temperatures is that they will often ask that the HVAC system be capable of quickly raising the room temperature as soon as the surgeon is done. This speedy room temperature rise also affects the HVAC design.

IV. Brief Literature Review Concerning Bair Hugger and Air Quality

There have been numerous studies regarding the possible impact of the BH on OR air quality, specifically over the OR table. Many peer reviewed studies have conducted particle and neutral buoyant bubble tests as well as temperature tests in field and lab experiments. Others have used computer models to simulate the effects of BH devices in operating rooms. Following is a summary of the literature that I have reviewed, followed by my interpretation of the relevance to Bair Hugger use in OR's.

1. *Forced-air warming and ultra clean ventilation do not mix.* THE JOURNAL OF BONE AND JOINT SURGERY. McGovern, Albrecht, Belani, Nachtsheim, Partington, Carluke, and Reed, 2011. These authors used neutral buoyancy bubbles to observe air flow in an OR, and found bubble counts over the surgical table were higher when the BH was used compared to a non-convective warming blanket. Microorganisms in infections "were predominately skin commensals". This indicates generation of the particles occurred within the OR as particles this size (~10 microns) are easily collected in HVAC filters. While they were many variables, "regression identified a significant reduction in infection rates for the conductive fabric v. forced air warming". "Forced air warming had a significant and disruptive impact on the clean airflow patterns over the surgical site…established convection currents that mobilized resident air from….. the floor".
2. *Airborne Respiratory Diseases and Mechanical Systems for Control of Microbes.* HEATING PIPING/AIR CONDITIONING, Kowalski and Bahnfleth, 1998. Seminal article, included in full in the 1st ed. ASHRAE HVAC Design

Manual, 2003. Table 3 confirms estimates of cfu/m3 to match Gaison & Goddard as cited in Figure 7 of this report. Figure 1 shows the size of common bacteria to be 0.3-1 micron.

3. *FDA Executive Summary On Heating/Cooling Devices, Medical Devices Advisory Committee, June 2, 2016*

   While this article focused on heating/cooling devices during cardiothoracic surgery, some of their observations are pertinent to engineers considering the Bair Hugger device, namely:

   a. "the most likely source of patient infection is through OR air"

   b. "Turbulent airflow is undesirable in a surgical environment as it disrupts the unidirectional vertical air flow protection over the surgical field. It is therefore believed that when the protection provided by the laminar vertical air flow is disrupted, particles such as NTM may remain suspended in the air, traveling on air currents, until reaching the surgical field."

   c. "..fans may facilitate the movement of aerosolized NTM from inside the unit into the operating room, and possibly into the sterile surgical field (via laminar flow disruption)"

4. *Do forced air patient warming devices disrupt unidirectional downward airflow?* THE JOURNAL OF BONE AND JOINT SURGERY, Legg, Cannon, and Hamer, 2012;

   a. "Forced air warming resulted in a significant mean increase in temperature (1.1C v 0.4C, $p<0.0001$) and number of particles (1038.2 v 274.8, $p=0.0087$) over the surgical site when compared to radiant warming"

   b. Measured 0.3, 0.5, and 5 micron particles

5. *Convection Warmers: not just hot air.* ANESTHESIA 1997:52:1073-1076. Avidan MS, Jones, N et al.

   a. Blew air from BH onto agar plate. Of 10 devices "four grew potentially pathogenic organisms". Aspergillus fumigatus, staphylococcus xylosus, etc.

   b. But didn't find organisms growing from air ejected from blanket.

c. CFU on outside of filter, but not inside;

d. Colonies were found in 3 hoses;

e. Put filters on BH hose exhaust. Did not detect pathogenic organisms;

f. Recommend always use perforated blankets, add a microbial filter on hose, insure hoses are sterilized regularly.

6. *Do warming blankets increase bacterial counts in the operating field of a laminar flow theatre?* THE JOURNAL OF BONE AND JOINT SURGERY, 2002;84-B:486-8 Sharp, Chesworth, Fern

   a. "Smoke test revealed that the blanket air flow had no significant effect on the theatre airflow";

   b. "No colonies were grown in any of the groups tested and our results suggest that the patient warming system does not influence bacterial counts at the operating site in an ultraclean air-ventilated theatre, even with patients who have high shedding of skin cells". "The Warm Touch ….does not increase the number of CFU's at the operating site";

   c. "The HEPA filter in the warming unit therefore appeared to be fully functional" vis a vis high levels at floor.

7. *Forced-air patient warming blankets disrupt unidirectional airflow.* THE JOURNAL OF BONE AND JOINT SURGERY. Legg and Hamer, 2013;

8. *Patient Warming Excess Heat: The Effects of Orthopedic Operating Room Ventilation Performance.* ANESTHESIA & ANALGESIA. Belani, Albrecht, McGovern, Reed, and Nachtsheim, 2013;

9. *Forced-Air Warming Does Not Worsen Air Quality in Laminar Flow Operating Rooms.* ANESTHESIA & ANALGESIA. Daniel I. Sessler, MD,* Russell N. Olmsted, MPH, CIC, SJMHS,† and Ruediger Kuelpmann, MSc, PhD, 2011.) The European OR's used in this study had far greater air flow than US 5,000 cfm v. 2,000 cfm. Depending on the configuration of the laminar diffuser, this could make for a much different supply air flow pattern. From the photo, the sampler intake appears to have been pointed upward, thus it would have gotten a larger sample of clean supply air. They introduced 35,000,000 particles per m3; they acknowledge this is much higher than a

normal OR. This baseline is then used for the statistical analyses. Compared to this very large number "small differences" are insignificant. The particle concentration without BH was 1,000 part/m3 while with the BH is was 9,000 part/m3. Thus, a 9 times increase with the BH on. I believe the differences would have been significant with a smaller baseline concentration.

10. Deposition of Corporate Representative of 3M – Al Van Duran.

    3M also admits that all data that is currently available indicates that the Bair Hugger increases particles over the sterile surgical site. Mr. Van Duran states that 3M did not test the filter assembly after installation in the BH. Instead they relied on the results of lab testing by the filter manufacturer. As noted in section d, above, Standard -170 Committee is likely to require testing of filter assemblies after installation in hospitals. I would expect similar testing by manufacturers of medical equipment.

11. **Deposition of Crowder, taken 3/16/17**

    a. Pentair gave 3M a price for HEPA;
    b. 3M had never asked for testing of filters by Pentair until July 2016;
    c. Internal documents confirm "there have been numerous discussions about changing filter efficiency";
    d. A MERV 17 filter is a "HEPA" filter. ASHRAE Std 52.2 sets the standards for performance of HVAC filters.
    e. 3M declined to adopt a higher efficiency filter because it would have added manufacturing cost and increased pressure drop.

12. 2006.2.26 Filter Test by Camfil-Farr

    a. Flat filter efficiency measured at 72% @ 0.4 micron. MERV 14 is 75-85% @ 0.3-1 micron, so the filter 3M uses is MERV 13 at best. Per ASHRAE chart, MERV 13 and 14 typically are rigid box filters 6-12" deep. This was flat filter 2".

    b. "No direction of air flow marked n filter. Pleats look irregular"

13. *Effect of forced air warming on the performance of operating theatre laminar flow ventilation.* Anesthesia. Dasari, Albrecht, and Harper, 2012;

14. *Resistive-polymer versus forced-air warming: comparable efficacy in orthopedic patients.* ANESTHESIA & ANALGESIA. Brandt S, Oguz R, Hüttner H, Waglechner G, Chiari A, Greif R, Kurz A, Kimberger O, 2010.) Researchers found the temperature of the air above the surgical site is statistically

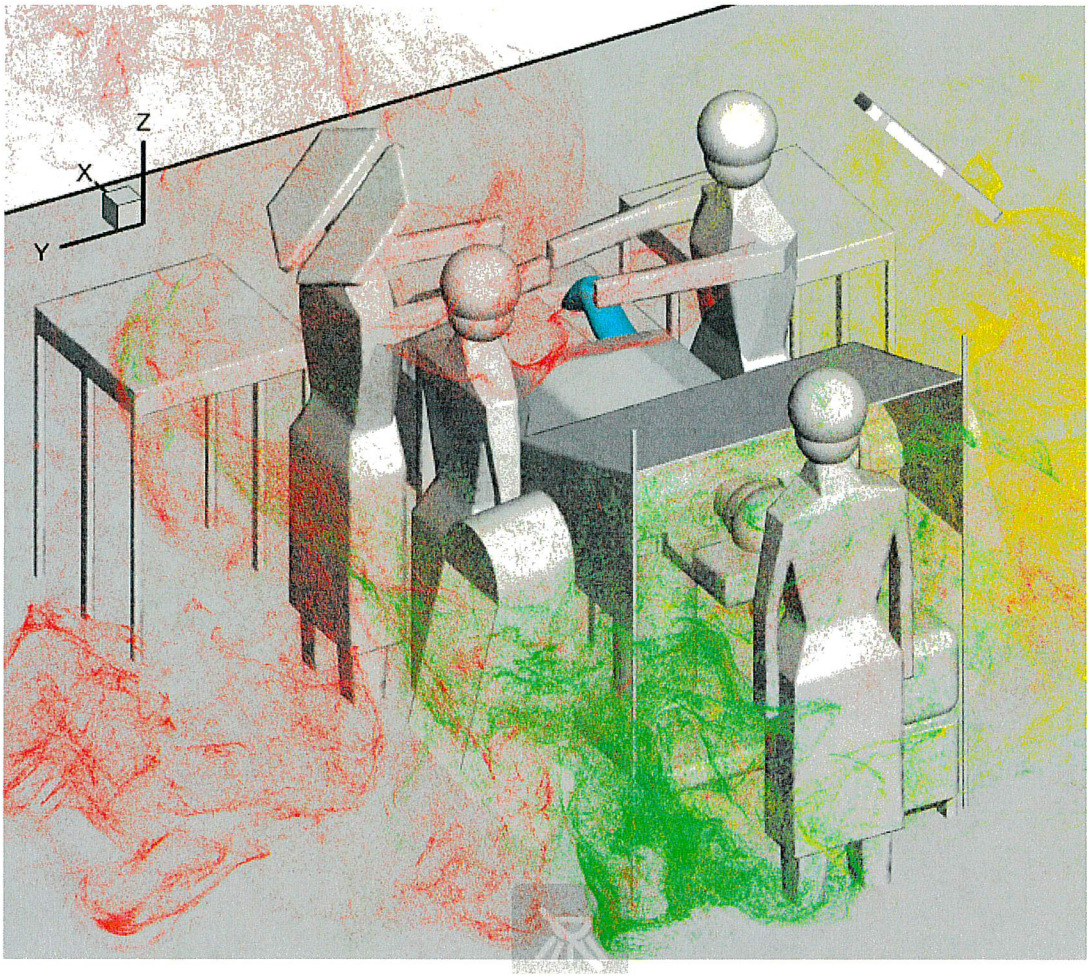
significantly greater when the Bair Hugger device is on as compared to off or compared to other patient warming devices.

15. *Effect of Heated-Air Blanket on the Dispersion of Squames in an Operating Room*. Said Elghobashi, 2017. Computational fluid dynamics analysis of a Bair Hugger device in an operating room environment, it is shows that the Bair Hugger device can significantly increase turbulence around the surgical table that increases the likelihood of squames from the floor to reach the sterile site, as shown in the following diagram:

806 and blower-on cases. With the blower-off, the majority of the squames are dispersed by the
807 ventilation air flow towards the outlet grilles. None of the squames actually rise to the level of
808 the side tables or the OT. In contrast, with the blower-on, a large number of squames are lifted
809 upwards by the rising thermal plumes. Some of the squames are lifted above the surgeons

61

810 heads and are blown towards the OT by the downward moving ventilation air. Large number
811 of squames are seen to be above the OT, several are surrounding the surgeons hands, above
812 the side tables, and some are very close to the patient's knee and the surgical site. Majority of
813 the squames that come close to the surgical site were found to have originated from the sides
814 parallel to the length of the OT.



V. Bair Hugger Filtration

Given the velocity of the air entering the BH, it is clear that it will entrain particles from the floor and blow them into the blanket. Figure 7 shows measured colony forming units (cfu) in hospitals. Although this is from 1968, it is still considered to be a seminal study. If we assume the air near the floor of an OR is as clean as a standard hospital which meets ASHRAE minimum standards, that is 10 cfu/cf. The BH 505 processes about 50 cfm, so 500 cfu/min = 30,000 cfu/hr will enter the unit. Even if the filter itself was 95% effective – and we know from 3M

documents the filter is far less than 95% effective - with leaks the assembly is reduced to 90% effective, which means ~3,000 cfu/hr will be blown into the hose. In that instance it is likely most of particles will enter the blanket and some of them will be ejected from the blanket pinholes. Even if only10% of the particles are ejected, then at least 300 cfu/hr are blown near the patient.

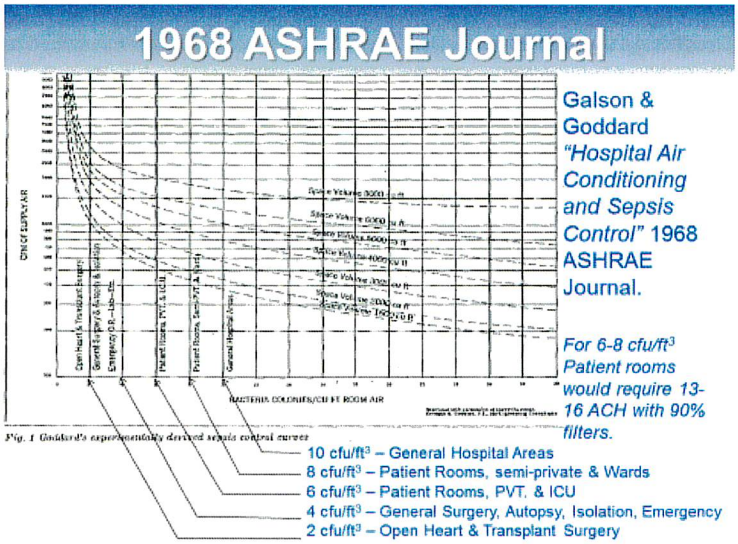


Figure 7. Colony Forming Units in Air

VI. Summary of Opinions

While there is some discrepancy in the literature, there are several aspects of the Bair Hugger device which, in my opinion, obviously compromise the performance of the OR HVAC system.

The following are based on physics and clear statements of fact:

1. The Bair Hugger operating in an OR will create turbulence at the floor, stirring settled particles;
2. The Bair Hugger draws particles off the floor into the unit. It functions much like like a household vacuum cleaner;
3. The performance of the filter assembly is not appropriately or correctly documented;

4. 50-100 cfm are blown from the blanket into or near the sterile field, causing air to move horizontally, while the intent of the HVAC system is to maintain downward air flow;
5. Air leaving the blanket at 100-110F will cause upward convective air flow;
6. The hot air will add to surgeon's discomfort, resulting in them requesting even lower temperatures in the OR. This will require colder air and result in higher downward air velocity causing additional turbulence at the boundary of the flow and where it sticks obstructions. For best results the flow of the clean air needs to be about 35 fpm;
7. The heater in the Bair Hugger adds to the cooling load, thus requiring more air and/or colder air than the initial design.

It is my professional opinion that the Bair Hugger compromises the sterility of the operating room by, at a minimum, the following:

1. The filters in the Bair Hugger are less efficient that those used in the HVAC system serving an OR.
2. The air velocity at the floor under the Bair Hugger is sufficient to entrain particles from the floor
3. The floor of every OR is non-sterile and usually bears heavy load of particles, many of which could be pathogenic.
4. The hot air from the Bair Hugger will interfere with the downward flow of clean air from the ceiling diffuser.

In summary, I believe that use of the Bair Hugger will adversely affect the air quality in the OR and at the patient. This will place the patient at increased risk of contracting an HAI.

I hold these opinions to a reasonable degree of professional engineering certainty. Additionally, I reserve the right to amend and/or supplement this report and these opinions if additional information becomes available to me.

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